

REMARKS/ARGUMENTS

Claims 17-23 and 30-44 are pending. Claims 17, 18, and 30-41 were examined, with the remaining claims having been withdrawn pursuant to a prior election of species requirement. The claims have been amended and canceled as noted above. Reexamination and reconsideration of the claims, as amended, are respectfully requested.

Claims 17, 30-41, and 44 were rejected as being anticipated by Beyerlein '279. Such rejections are traversed in part and overcome in part.

The Examiner asserts that Beyerlein "discloses in Figure 2 a method for injecting a pharmaceutical agent beyond the EEL of a coronary blood vessel by five millimeters or less and confirming the position of the needle." Applicants disagree with this characterization.

While Beyerlein illustrates an instance where a needle has been advanced beyond the EEL in Fig. 9 (not Fig. 2), nowhere does Beyerlein teach or suggest that the position of the needle is confirmed or that there would be any reason to confirm such position. As explained in the prior amendment, Beyerlein never teaches or suggests a method or protocol for confirming that the needle aperture has actually extended beyond the EEL into the adventitial tissue. Instead, Beyerlein confirms that the needle has extended fully from the needle deployment catheter and assumes that the confirmed depth, which could be anywhere from 0.25 mm to 4 cm (Par. 44) will be sufficient to extend into the adventitial tissue. No single needle length within that range, however, would be sufficient to assure positioning of the needle both beyond the EEL and in the adventitial tissue in all instances. Lengths which are short enough to assure not extending beyond target adventitial tissue would not necessarily be long enough to extend through the EEL. Conversely, lengths which are sufficiently long to assure extending through the EEL might well be too long and extend beyond the target adventitial tissue. For these reasons, Applicants maintain that the Examiner has not stated grounds sufficient to maintain the rejection for anticipation.

Nonetheless, Applicants are amending independent claim 17 to incorporate the features generally set forth in dependent claim 18, now canceled. Dependent claim 18 set forth that the confirming step comprises "injecting contrast media through the needle aperture and

observing distribution of the media” in order to confirm that the delivery aperture of the needle has penetrated into tissue beyond the EEL. Dependent claim 18 was rejected over Beyerlein as discussed above further combined with the teachings of Greff ‘714. Applicants respectfully disagree with this combination and rejection.

Greff discloses a generally conventional technique for locating an artery using an angiogram. The needle is advanced from the uterus into a uterine artery in order to occlude the artery for fibroid treatment. To indicate when the artery has been accessed, radiopaque dye is injected into the artery where it immediately disperses through the arterial blood flow.

Injecting contrast media into tissue beyond the EEL, as previously set forth in dependent claim 18, is not equivalent to performing an angiogram as taught by Greff. As claim 17 required that the delivery aperture be penetrated into tissue, the contrast media would enter the tissue and be distributed, in contrast to Greff which teaches introducing the contrast media into a major discrete artery.

Nonetheless, in order to further distinguish Greff, claim 17 has been further amended to require that the contrast media be observed to determine whether it “spreads longitudinally along a blood vessel wall indicating that the aperture is in the adventitial tissue” or alternatively whether “the media is constrained within the wall of the blood vessel in which case the aperture of the needle has not reached the adventitial tissue.” Support for this amendment is found, for example, in paragraphs 32 and 79 of the application as published. Moreover, by observing whether either of the two contrast distribution patterns exist, the appropriate position of the needle can be confirmed with confidence prior to complete injection of the drug.

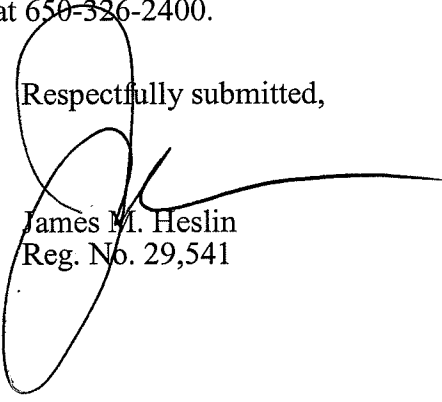
In view of the above amendments and remarks, it is believed that independent claim 17, as amended, clearly distinguishes the teachings of Beyerlein even when combined with those of Greff. Thus it is believed that independent claim 17, as well as all remaining claims depending thereon, are in condition for allowance, and requested that the application be passed to issue at an early date.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,


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